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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,450	12/05/2003	Christina Khoo	7129-00	1031

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Colgate-Palmolive Company
909 River Road
P.O. Box 1343
Piscataway, NJ 08855-1343

EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,450	KHOO ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 5 January 2006 to claim 19 has been entered. Claims 16, 18 and 20 have been cancelled. Claims 1-15, 17, and 19 remain pending in the current application, all of which have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15, 17, and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shields, Jr. et al (US Patent 6,156,355), in view of Wadsworth et al (US Patent 6,737,089), and Klimberg et al (*Arch Surg*, 1990).

Shields, Jr. et al teach a dog food composition, 'The Herding Diet' which comprises fermentable fibers, in the amount of 4.0%; omega-3 fatty acids, in the amount of 0.2%; antioxidants; and glutamine (See col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis'). The 'Herding Diet' is specially formulated for dogs that are prone to chronic GI inflammation and diarrhea; it is designed to be fed to dogs as a means of controlling GI inflammation and diarrhea (See col. 11, ln 18-28). Shields, Jr. et al teach that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the

immune system of the intestinal tract (See col. 12, ln 11-22); however, they do not disclose a precise amount of glutamine to include in the diet.

Wadsworth et al and Klimberg et al both provide similar teachings on the benefits of glutamine on intestinal health during times of gastrointestinal stress (such as bouts of diarrhea). Wadsworth et al teach glutamine, 5-10% wt, as an additive to animals' diets, specifically dog and cat diets, can provide improved digestive system support (See Wadsworth et al, col. 7, ln 51-60 and col. 13, ln 34-49 (Example 4)). Klimberg et al teach adding glutamine, 3% wt, to diets of rats suffering gastrointestinal distress from abdominal radiation, diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the amounts of glutamine specified by either Wadsworth et al or Klimberg et al (5-10% and 3%, respectively) in the diet disclosed by Shields, Jr. et al. Shields, Jr. et al already teach using glutamine in the diet in order to treat stressed GI tracts, however because they do not teach a specific amount of glutamine, one of ordinary skill in the art would have been motivated to use the amounts of glutamine taught by Wadsworth et al and Klimberg et al. One would expect success because all three teach that glutamine treats stressed GI tracts by providing the essential fuel for intestinal immune cells (See, e.g. Shields, Jr. et al, col. 12, ln 11-22).

Shields, Jr. et al does teach the importance of antioxidants as scavengers of oxygen, and terminators of free radicals, and therefore their inclusion in the diet (col. 5, ln 65- col. 6, ln 11). Shields, Jr. et al, however, do not teach a specific amount of antioxidants present in the diet. Wadsworth et al also teach inclusion of vitamins and antioxidants, such as vitamins A and E, in amounts from 0-10% by weight (See col. 5, ln 24-42). However, any pharmaceutical amount would be appropriate for these diets. Excess vitamins are flushed from the system; therefore, it would be obvious to include any amount of antioxidants, within a pharmaceutically accepted range, with expectations of the benefits and without concern of over dosage. Therefore, though

Shields, Jr et al is silent on the amount of antioxidants in their diet, it would have been obvious to include any amount within a pharmaceutical range, such as 0.1-3% by weight.

Though Klimberg et al uses rats as the experimental animal, and Wadsworth et al dogs and cats, it would have been obvious to extend the results to include dogs, as described by Shields, Jr et al, because they are all mammals, dogs, cats and rats all have simple digestive tracts, and it is known that glutamine has similar beneficial effects on all three species, it is simply the amount of glutamine that is extrapolated from Klimberg et al and Wadsworth et al. For the same reasons it would be obvious to extend the results of Shields, Jr. et al, in view of Klimberg et al and Wadsworth et al, to include cats and other non-canine species, such as rats; therefore, a diet of the same composition, including glutamine, fermentable fiber, omega-3 fatty acids, and antioxidants in the specified amounts, and use of such composition for the management of diarrhea, would be obvious for use in dogs as well as non-canine mammals, such as cats and rats (Claims 1-15, 17, and 19). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-15, 17, and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (*In Practice,* 2002).

Chandler teaches diets for dogs and cats for the treatment and control of gastrointestinal diseases, which result in symptoms such as diarrhea. Chandler et al teach that a diet, which includes fermentable fibers, omega-3 fatty acids, antioxidants, and glutamine, can benefit an animal with a stressed gastrointestinal tract (See Pg. 529, col. 2, and especially Pg. 533, col. 1). Chandler teaches a diet comprising these ingredients can be used as a treatment for gastrointestinal diseases (See especially Pg. 533).

Though Chandler is silent on the precise amounts of glutamine, fermentable fibers, omega-3 fatty acids, and antioxidants, it would have been obvious to a person of ordinary skill in

the art to experiment with varying amounts, within pharmaceutical ranges, of each ingredient to optimize the treatment potential of the diet. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Chandler teach that each specific ingredient plays an important role in maintaining and, in times of stress restoring gastrointestinal health (See especially, Pg. 529, col. 1- Pg. 531, col. 1). A person of ordinary skill in the art would have been motivated to increase the amount of fermentable fiber, omega-3 fatty acids, and antioxidants, and to include glutamine in a diet for a dog or cat with GI tract problems because these ingredients are highly digestible, the fiber promotes fecal bulk, the omega-3 fatty acids help to decrease inflammation, antioxidants promote immune response, and need to be replaced during bouts of diarrhea due to being flushed out, and glutamine has been found to provide energy for enterocytes during times of stress, boosting immune ability and GI health (See Chandler Pg. 529, col. 2- Pg. 533, col. 1). One would have expected success because Chandler describes a diet containing these ingredients as a means for treating GI problems (See Chandler Pg. 529, col. 2- Pg. 533, col. 1) (Claims 1-15, 17, & 19). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 5 January 2006 have been fully considered, but are not found persuasive. Specifically applicant argues the examiner has not established a *prima facie* case of obviousness, and even if a *prima facie* case of obviousness was established, applicants state they have shown unexpected results that rebut any such case. Applicants argue that Shields, Jr et al do

not teach or suggest ameliorating diarrhea in a mammal having a GI tract inflammation; applicants also state that Shields, Jr et al is silent with regards to specific amounts of glutamine or omega-3-fatty acids contained in the described diets. Applicants argue that neither Wadsworth et al nor Klimberg et al overcome the deficiencies of Shields, Jr et al because Wadsworth et al does not teach the importance of glutamine in their composition and Klimberg et al do not teach or suggest alleviating diarrhea in a patient suffering from GI tract inflammation. Applicants further argue that Chandler et al do not teach or suggest the claimed combination of components in the claimed concentrations.

In response to applicants' arguments that Shields, Jr. et al, in view of Wadsworth et al and Klimberg et al do not teach or suggest ameliorating diarrhea in a mammal, it is noted that Shields, Jr. et al does, in fact, teach a diet comprising glutamine, fermentable fibers, omega-3-fatty acids, and antioxidants is intended to control GI inflammation and diarrhea (See Shields, Jr et al, col. 11, ln 18-28). Furthermore, each of the cited references teach that diets comprising the claimed components, particularly glutamine, are capable of improving gastrointestinal health. Specifically, Shields, Jr. et al teach that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See Shields, Jr et al, col. 12, ln 11-22); Wadsworth et al teach glutamine can provide improved digestive system support (See Wadsworth et al, col. 7, ln 51-60 and col. 13, ln 34-49 (Example 4)). Klimberg et al teach glutamine, when added to the diets of rats suffering gastrointestinal distress from abdominal radiation, diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2). Diarrhea is a sign of diminished intestinal health (See Taber's Cyclopedic Medical Dictionary, 1997); therefore, administering the diets disclosed in the references to improve overall gastrointestinal health would inherently manage diarrhea. Under the principles of inherency, if a prior art method, such

as administration of the diets disclosed in the references, in their normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art method. When the prior art method is the same as a method described in the specification for carrying out the claimed method, it can be assumed the method will inherently perform the claimed process. See *In re Best*, 562 F. 2d, 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and *Ex parte Novitski*, 26 USPQ 2d 1389 (Bd. Pat. App. & inter. 1993).

Applicants further attack each reference individually, arguing that none of the individual references teach all of the claimed components in the claimed concentrations. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Shields, Jr. et al teach a composition comprising 4.0% fermentable fibers, 0.2% omega-3 fatty acids, antioxidants, and glutamine (See Shields, Jr. et al, col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis'); while Shields, Jr. et al is silent on the amounts of glutamine and antioxidants, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Klimberg et al and/or Wadsworth et al who teach mammalian diet compositions comprising 3% and 5-10% glutamine, respectively, the amount of antioxidants included in the diet would have been routinely optimized by one of ordinary skill in the art. Therefore, when viewed in combination, the cited references do, in fact, teach a composition comprising the claimed components, in the claimed concentrations, which can be administered to a mammal to improve gastrointestinal health, which inherently includes management of diarrhea.

In response to applicants arguments that Chandler et al do not teach or disclose the claimed components in combination, or in the claimed concentrations, it is noted that Chandler et al teach that each of the claimed components are useful for treatment of gastrointestinal diseases that result in symptoms such as diarrhea. The motivation to combine the components taught by

Chandler et al, each intended for the same purpose (treatment of stressed gastrointestinal tract) comes from the well established principle of patent law that it is prima facie obvious to combine two or more compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Regarding the specific concentrations of each claimed component, the examiner maintains that it would have been well within the purview of one of ordinary skill in the art to routinely optimize the concentrations of each component taught by Chandler et al to arrive at the claimed composition. As stated previously, it is well established in patent law that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it is maintained that one of ordinary skill in the art would have been able, by routine experimentation, to optimize the concentrations and amounts of the disclosed ingredients.

In response to applicants arguments based on their 'unexpected results' presented in Example 2 on pages 4 and 5 of the specification, the results presented in Example 2 are not found to be indicative of any unexpected results, and thus are not persuasive. The results shown in Example 2 show that diets including all four claimed components (glutamine, antioxidants, omega-3-fatty acids, and fermentable fibers) improved stool samples better than diets lacking two of the claimed components (glutamine and antioxidants); the results do not show that the claimed concentrations of the claimed components were critical to the improvement, in fact they are silent with respect to the concentrations. The cited references teach the individual benefits of each of

the claimed components have on gastrointestinal health; therefore it would be expected that combination of all the claimed components (such as in Food "C") would have a greater total beneficial effect on gastrointestinal health (measured by stool quality) than combinations of fewer than all four claimed components (such as in Foods "A," "B," and "D"). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effects of the ingredients. See *In re Sussman*, 58 USPQ 262 (CCPA 1943). Therefore, combination of all four claimed ingredients, each known to benefit the GI tract, would be expected to affect a greater improvement on GI health, as indicated by stool quality, than combinations of less than all four claimed ingredients. The concentrations of each component would be routinely optimized by one of ordinary skill in the art, as the example provided by applicants shows no unexpected benefits related to the specifically claimed concentrations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651